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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,986	02/05/2004	Jenny Louie-Helm	3100-0003.10	7141

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REED INTELLECTUAL PROPERTY LAW GROUP
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,986	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/05/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 12/05/05; request for continued examination under 37 CFR 1.114, amendment and remarks filed 11/30/05. Claims 1-26 are pending.

Claim Rejections - 35 USC § 102

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/30/05 has been entered, although applicants now claim tablet instead of any dosage form claimed.

The prior art Mehra was dropped in the final rejection. Upon further consideration, the claims are obvious over Mehra and the rejection is now made.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al. (US 5,830,576).

Mehra discloses a diuretic formulation that comprises sodium carboxymethyl cellulose or hydroxypropylmethyl cellulose or methylcellulose or alginate or carrageenan (column 3, lines 38-42, Example 19), the formulation is made into tablet dosage form (abstract) and Mehra uses

the USP disintegration test to determine the disintegration of the formed granules (column 8, lines 13-20). The formulation further contains lubricants and examples of lubricant used are talc, fatty acid esters and polyethylene glycol (column 4, lines 11-18). Dextran, guar gum, carrageenan , alginates, hydroxypropyl cellulose and carboxymethylcellulose are listed as suspending agents (column 3, lines 38-46). Methylcellulose is listed in instant claim 6 as a hydrophilic polymer. In general, the release profile of dosage forms is a predetermined condition when dosage forms are formulated as is evident in the matrix polymers used with the active agent that would make a dosage form controlled release or immediate release; and in general in vitro test analysis correlate in vivo pattern of drug release. While Mehra does not specifically disclose correlation between release profile and disintegration and relating disintegration with selecting an optimized controlled release dosage form, Mehra discloses determining tablet disintegration time and effectiveness of excipient for tabletting active agents such as agricultural chemicals (column 8, lines 16-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the time the invention was made to prepare the tablet dosage form of Mehra and determining the disintegration of the dosage form to determine which excipients are more effective for tabletting based on the disintegration. One having ordinary skill in the art would have been motivated to use the disintegration data to correlate effectiveness of excipient for tabletting since release of active agents may in part be due to how well or not the dosage forms disintegrate.

4. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friend et al. Franz et al. (US 5,232,704) in view of O'Neil et al. (US 4,704,405).

Franz discloses using in vitro release study in anticipation that the release profile of prepared dosage formulation would be sustained according to the in vitro release study data (column 9, lines 7-30; column 12, lines 25-50; abstract); the formulation comprises active ingredient such as prostaglandin and non-steroidal anti-inflammatory drug (column 3, lines 15-33; column 4, lines 4-10), hydroxypropyl methylcellulose, carboxymethylcellulose and PVP or polyethylene glycol (column 5, lines 15-33). Frantz administers the formulation to subject in the fed state and once daily (column 14, 36-44).

Franz disclose release profile of capsules of anti-inflammatory agents determined by disintegration. Franz does not disclose a tablet. O'Neil disclose NSAID's formulated as tablet (abstract; column 2; column 3, lines 11-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the NSAID containing composition for administration to a subject in the fed state. It is known in the art and as disclosed by O'Neil that NSAID's can be formulated as tablets. It would have therefore been a motivation to prepare and use composition of Franz in tablet form as disclosed by O'Neil with the expectation that the formulation would release the active agent according to disintegration profile.

Response to arguments:

The rejection of claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (US 5,972,389 cited by applicants in the specification) in view of applicants' admitted prior art is not made and applicants' argument with respect to this rejection is persuasive.

The rejection of claims 1-8, 10-13, 17, 18 and 26 under 35 USC 102(b) as anticipated by Franz et al. (US 5,232,704) is not made in this RCE application in view of applicants' persuasive because Franz discloses a tablet.

Double Patenting

The cancellation of claims 49-51 overcomes the provisional double patenting rejection.

Other matters:

Claims 1-26 are examined. However, claim 17 is a method of delivering pharmacologically active agent to the upper GI, while claim 1 is a method of selecting an optimized controlled release dosage form. Claim 17 and claim 1 are capable of supporting different patents within the art. It is respectfully requested of applicants to comment/discuss or provide any reasons why invention 1, represented by claim 1 and invention II represented by claim 17 may be equivalent and as such may not be restricted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600